

Application No. 10/540,522  
Art Unit: 1651

Amendment  
Attorney Docket No. 052767

**AMENDMENTS TO THE DRAWINGS**

The attached replacement sheet of drawing includes changes to Fig. 1.

### **REMARKS**

Claims 1-30 are pending in the present application. Claims 1-10 and 19-30 are rejected. Claims 1, 8, 9, 19, 27-30 are herein amended. Claims 2-7, 10 and 20-26 are herein cancelled without prejudice. New claims 31-35 are added herein. No new matter has been added. Applicants thank the Examiner for the courtesies extended in the telephone interview of March 16, 2011. Applicants' Statement of the Substance of the Interview is incorporated herein.

### **Objections to the Drawings**

The Office Action objects to Figure 1, because it fails to show a fixed support of the cultivating container 2. The Office Action notes that the cultivating container 2 is not illustrated as being attached to the inner frame 7. Applicants herewith submit a revised Figure 1 in which the lines of the outer frame 5 which are visible through the inner frame 7 (upper part) are deleted. As such, the cultivating container 2 appears connected to the inner frame 7. Favorable reconsideration is respectfully requested.

### **Applicants' Response to Claim Rejections under 35 U.S.C. §112**

**Claims 1-10 and 19-30 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The Office Action indicates that the claims are indefinite for several reasons. As a preliminary comment, Applicants herein rewrite the claims generally in order to improve clarity

and form. The claimed embodiments are a two-step process, with the first being establishment of a micro-gravity environment, and the second being the establishment of a hyper-gravity environment.

As to claim 1, the Office Action states that it is unclear if steps (a) and (b) can be performed at the same time, or if they are sequential. Based on page 11, line 27 to page 12, line 4 for example, step (b) is performed after step (a). Therefore, Applicants herein amend the claims to clarify this. Furthermore, in order to clarify the claims, Applicants amend step (a) of claim 1 to recite rotating about at least two orthogonal axes, and amend step (b) of claim 1 to recite applying at least a centrifugal force by rotating about one axis.

As to the claims which are dependent on claim 1, Applicants herein make various amendments in order to improve clarity and form.

With regard to claim 19, Applicant's herein amend this claim to more clearly recite the function attributed to the "means." Generally, Applicants amend claim 19 in a manner similar to claim 1. Applicants also amend the claims dependent on claim 19 in a manner similar to the claims dependent on claim 1.

With regard to claim 29, the Office Action rejects this claim because it is a method claim which dependent on an apparatus claim. Claim 29 was intended to be dependent on claim 28. Applicants amend claim 29 as such. Favorable reconsideration is respectfully requested.

**Applicants' Response to Claim Rejections under 35 U.S.C. §102**

**Claims 1-3, 5-8, 19-21 and 23-26 are rejected under 35 U.S.C. §102(b) as being anticipated by Plett et al. (2001, *In Vitro Cell and Developmental Biology – Animal* 37: 73-78).**

It is the position of the Office Action that Plett discloses the embodiments as claimed. Plett is directed at proliferation of human hematopoietic bone marrow cells in simulated microgravity. In the “Materials and Methods” section, Plett discloses the use of a rotating wall vessel (RWV) system, which simulates micro-gravity by vertical rotation. This only includes one axis of rotation.

In response, Applicants respectfully submit that amended claims 1 and 9 distinguish over Plett at least because they recite multi-axis rotation in step (a). Additionally, amended claim 1 recites a subsequent step (b) of applying a centrifugal force. Plett does not disclose or suggest any such subsequent step. Therefore, Applicants respectfully submit that Plett does not disclose or suggest the embodiment as claimed. Favorable reconsideration is respectfully requested.

**Claims 19-27 are rejected under 35 U.S.C. §102(e) as being anticipated by Yugen Kaisha ECT (“Yugen”) (JP 2002-045173).**

Yugen is directed at a bioreactor. Yugen appears to disclose a bioreactor which can rotate a chamber along the X-axis and Y-axis. See paragraphs [0025] and [0026].

Claim 19 recites the apparatus, as a first means and a second means. In response, Applicants respectfully submit that Yugen does not disclose or suggest a means which applies a centrifugal force by rotating about one axis.

Additionally, Applicants herein add new claims 34 and 35. Claim 34 clarifies that the first and second means are the same and are similar to what is illustrated in Figure 3. Yugen does not disclose or suggest this. Furthermore, claim 35 clarifies that the first and second means are different. For example, the first means can be similar to what is illustrated in Figure 1, while the second means can be similar to what is illustrated in Figure 2. Yugen does not disclose or suggest a system having two components like that of Figures 1 and 2. Favorable reconsideration is respectfully requested.

**Claims 19-27 and 29 are rejected under 35 U.S.C. §102(e) as being anticipated by Uemura et al. (“Uemura ‘800”) (U.S. Patent Application Publication No. 2003/0041800).**

It is the position of the Office Action that Uemura ‘800 discloses the embodiments as claimed. Uemura ‘800 is directed at an application apparatus of 3-dimensional klinostat and growing method using the same. As illustrated in Figure 1, Uemura ‘800 discloses a device capable of X-axis and Y-axis rotation, similar to the device illustrated in Figure 1. Uemura ‘800 does not disclose or suggest a subsequent step of applying a force different from gravity.

Claim 19 recites the apparatus, as a first means and a second means. In response, Applicants respectfully submit that Uemura ‘800 does not disclose or suggest a means which applies a centrifugal force by rotating about one axis.

Additionally, Applicants herein add new claims 34 and 35. Claim 34 clarifies that the first and second means are the same and are similar to what is illustrated in Figure 3. Uemura '800 does not disclose or suggest this. Furthermore, claim 35 clarifies that the first and second means are different. For example, the first means can be similar to what is illustrated in Figure 1, while the second means can be similar to what is illustrated in Figure 2. Uemura '800 does not disclose or suggest a system having two components like that of Figures 1 and 2. Favorable reconsideration is respectfully requested.

**Applicants' Response to Claim Rejections under 35 U.S.C. §103**

**Claims 1-10 and 19-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Plett in view of Goodwin (U.S. Patent No. 5,496,722), Matthews et al. (U.S. Patent No. 5,851,984) and Yugen Kaisha ECT (JP 2002-45173).**

It is the position of the Office Action that Plett discloses the embodiments as claimed, with the exception of teaching (i) first expanding stem cells in a culture container then differentiating the same cells in the same container and (ii) a multi-axis apparatus. The Office Action relies on Goodwin and Matthews to teach (i) and relies on Yugen Kaisha to teach (ii).

Goodwin is directed at a method for producing non-neoplastic, three dimensional, mammalian tissue and cell aggregates under microgravity culture conditions and the products derived therefrom. Like Plett, Goodwin discloses the use of a rotating wall vessel (RWV).

Matthews is directed at a method of enhancing proliferation or differentiation of hematopoietic stem cells using WNT polypeptides. Matthews teaches the use of differentiation factors.

In response to the pending rejection, Applicants respectfully submit that none of the cited art, either singly or in combination, discloses step (b) of claim 1. Amended claim 1 recites a subsequent step (b) of applying a centrifugal force. Therefore, Applicants respectfully submit that the combination of cited art does not disclose or suggest the embodiment of claim 1.

Claim 19 recites the apparatus, as a first means and a second means. In response, Applicants respectfully submit that the cited art, either singly or in combination, does not disclose or suggest a means which applies a centrifugal force by rotating about one axis.

Additionally, Applicants herein add new claims 34 and 35. Claim 34 clarifies that the first and second means are the same and are similar to what is illustrated in Figure 3. The cited art, either singly or in combination, does not disclose or suggest this. Furthermore, claim 35 clarifies that the first and second means are different. For example, the first means can be similar to what is illustrated in Figure 1, while the second means can be similar to what is illustrated in Figure 2. The cited art, either singly or in combination, does not disclose or suggest a system having two components like that of Figures 1 and 2. Favorable reconsideration is respectfully requested.

**Applicants' Response to Double Patenting Rejections**

**Claims 19-27 and 29 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 15, and 16 of U.S. Patent No. 7,163,821 ("Uemura '821").**

It is the position of the Office Action that system claims are not patentably distinct from the claimed subject matter in Uemura '821.

Claim 19 recites the apparatus, as a first means and a second means. In response, Applicants respectfully submit that Uemura '821 does not claim, disclose or suggest a means which applies a centrifugal force by rotating about one axis.

Additionally, Applicants herein add new claims 34 and 35. Claim 34 clarifies that the first and second means are the same and are similar to what is illustrated in Figure 3. Uemura '821 does not claim, disclose or suggest this. Furthermore, claim 35 clarifies that the first and second means are different. For example, the first means can be similar to what is illustrated in Figure 1, while the second means can be similar to what is illustrated in Figure 2. Uemura '821 does not claim, disclose or suggest a system having two components like that of Figures 1 and 2. Favorable reconsideration is respectfully requested.



**Claims 1-10, 28 and 30 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 7,112,441 (“Uemura ‘441”) in view of Plett, Goodwin and Matthews.**

It is the position of the Office Action that the method claims are not patentably distinct from the claimed subject matter in Uemura ‘441. The Office Action relies on similar reasoning as the §103 rejection above.

In response to the pending rejection, Applicants respectfully submit that none of the cited art, either singly or in combination, claims, discloses or suggests step (b) of claim 1. Amended claim 1 of the pending application recites a subsequent step (b) of applying a centrifugal force. The cited art, either singly or in combination, does not claim, disclose or suggest any such subsequent step. Therefore, Applicants respectfully submit that claim 1, and all claims dependent thereon, are patentably distinct from the claimed subject matter of Uemura ‘441, as modified by the cited art. Favorable reconsideration is respectfully requested.

**Claims 1-10, 28 and 30 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 7,297,500 (“Uemura ‘500”) in view of Plett, Goodwin and Matthews.**

It is the position of the Office Action that the method claims are not patentably distinct from the claimed subject matter in Uemura ‘500. The Office Action relies on similar reasoning as the §103 rejection above.

In response to the pending rejection, Applicants respectfully submit that none of the cited art, either singly or in combination, claims, discloses or suggests step (b) of claim 1. Amended claim 1 recites a subsequent step (b) of applying a centrifugal force. The cited art, either singly or in combination, does not claim, disclose or suggest any such subsequent step. Therefore, Applicants respectfully submit that claim 1, and all claims dependent thereon, are patentably distinct from the claimed subject matter of Uemura '500, as modified by the cited art. Favorable reconsideration is respectfully requested.

For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

If the Examiner deems that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

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If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,  
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Enclosure: Replacement drawing sheet including revised Figure 1